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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/582,492	03/06/2002	Elizabeth S. Light	142/003/PCT	8768

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VENTANA MEDICAL SYSTEMS, INC.
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EXAMINER
SWITZER, JULIET CAROLINE

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 06/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/582,492	LIGHT ET AL.	
	Examiner	Art Unit	
	Juliet C. Switzer	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *8-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 17-22* is/are rejected.

7)☒ Claim(s) *4* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-7 and 17-22, drawn to reagents for detecting human papillomavirus DNA.

Group II, claim(s) 8-16, drawn to methods of detecting human papilloma virus DNA.

2. The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The subject matter of at least claim 1 is anticipated in the prior art. For example, Troncone *et al.* (J Clin Path 1992; 45:308-313) teach a reagent for detecting human papilloma virus which comprises a plurality of DNA probes capable of specifically hybridizing to high-risk HPV DNA but not low-risk HPV DNA. Specifically, Troncone *et al.* teach a cocktail of HPV probes that would hybridize to HPV types 16, 18, and 33 (p. 309). Thus, there is no special technical feature that joins the methods of group I and the products of group II since the broadest embodiment of the products of group I is anticipated in the prior art.

3. During a telephone conversation with Hu W. Jones on 5/20/03 a provisional election was made with traverse to prosecute the invention of I, claims 1-7 and 17-22. Affirmation of this election must be made by applicant in replying to this Office action. Claims 8-16 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Objections

5. Claim 4 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 4 does not further limit the products of claim 1 because it further modifies only the intended use of the products but does not impose any further structural limitation on the claimed products.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-7 and 17-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite over the recitation of "capable of specifically hybridizing" because capability is a latent characteristic and the claims do not set forth the criteria by which to determine capability. That is, it is not clear whether the recited probes have the potential to specifically hybridize or do in fact hybridize to the high-risk HPV DNA. Amendment of the claim to read, for example, "which hybridize" would obviate this rejection. The remaining rejected claims are indefinite because they depend from claim 1 but do not remedy this deficiency in the claim.

Claim 1 is further indefinite over the recitation of "high-risk HPV DNA" and "low-risk HPV DNA" because the claims do not set forth the standards by which to determine the relative risk level of a particular HPV DNA. That is, there is no art established clear standard for the determination of which HPV DNA is "high" versus "low" risk DNA. For example, the instant claims include HPV types 31, 33, and 51 as "high risk" types, while these types are also known in the literature as "medium" risk HPV types (see Gomez *et al.* Eur. J. Histochem., Vol. 36, pages 137-142, 1992, p. 141, last sentence first paragraph). Thus, in light of the lack of a clear definition of high versus low risk HPV types is not possible to know from the claims which do not recite particular HPV types which types are considered "high" risk within the scope of the claims and which are considered "low" risk.

Claim 7 and claim 22 are indefinite because the claim recites that the probes are present in recited "amounts" but then lists a series of percentages for each probe. The claim does not set forth what the percentages are portions of (i.e. total hybridization mix, probe mix, etc), and it does not set forth how the percentages represent particular amounts.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7 and 17-22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejected claims are drawn to reagents for detecting human papilloma virus DNA in a cell sample which comprise a plurality of DNA probes capable of specifically hybridizing to high-risk HPV DNA but not low-risk HPV DNA. Dependent claims included in the rejection recite particular HPV types which hybridize to the probes and particular probes which do not, recite that the probes are "full length," and include specific concentrations of particular probes in the reagent. The claims do not set forth any particular sequences or structure for the probes, and in fact only identify the claimed nucleic acids in terms of their function. The genus of the claimed reagents, therefore, includes any probe which is specific to any HPV type that is known to cause cancer, a genus which includes hundreds of thousands of possible reagents. Even for claims which recite particular HPV types, these claims encompass any set of oligonucleotide probes which would hybridize specifically to the recited types. The claims which recite "full length" probes are themselves quite broad, since the definition of "full length" in the specification is inclusive of "sequence variations and shortening of the probe length (specification page 5)." From applicant's specification, Applicant appears to be in possession of a single probe combination which meets the functional limitations of the instant claims, that is a probe set that six separate plasmids, with one plasmid containing the whole genome of a HPV type and the six types being 16, 18, 31, 33, 35, and 51, wherein types 18, 33, 25, and 51 are present at 0.5 nanograms per milliliter of solution and types 16 and 31 re present at 0.2 nanograms per milliliter of solution (see p. 13, example 3), since this is the only reagent demonstrated by applicant to specifically hybridize only to those "high risk" types of HPV designated by Applicant, and not to "low risk" HPV, see Table 5. Thus, applicant has express

possession of only one species in a genus which comprises hundreds of millions of different possibilities.

With regard to the written description, all of these claims encompass reagents comprising nucleic acid sequence different from those disclosed in the specific reagents which for which no written description is provided in the specification.

It is noted that in Fiers v. Sugano (25 USPQ2d, 1601), the Fed. Cir. concluded that

> "...if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated...conception of any chemical substance, requires definition of that substance other than by its functional utility."

In the instant application, only a single reagent meeting the functional limitations of the claims is described, yet hundreds of thousands of possible reagents are encompassed by the claims. Also, in Vas-Cath Inc. v. Mahurkar (19 USPQ2d 1111, CAFC 1991), it was concluded that:

> "...applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed."

In the application at the time of filing, there is no record or description which would demonstrate conception of reagents modified from the single example given but possessing the functional characteristics required by the claims.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1, 2, 4, 5, and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Meijer *et al.* (WO 95/22626).

Meijer *et al.* teach a reagent for detecting human papillomavirus DNA comprising a plurality of DNA probes capable of specifically hybridizing to high-risk HPV DNA but not low-risk HPV DNA. In particular, Meijer *et al.* teach a mixture of probes specific for HPV types 16, 18, 31, 33, 35, 39, 45, 51, 52, 54, 56, and 58, and that this mixture does not contain probes specific for a variety of "low risk" HPV types (p. 16, lines 15-23).

With regard to claim 5, these probes are considered "full length" because an entire probe is given, and Meijer *et al.* teach using the full length of the probe in the reagent. The claim does not further define "full length" and thus the broadest reasonable interpretation of the claim is given.

With regard to claim 6, which recites that the reagent is "consisting essentially of" DNA probes to HPV types 16, 18, 31, 33, 35 and 51, in accordance with MPEP 2111.03, this transitional language is being interpreted to be the equivalent of "comprising" as there has been no clear indication in the specification of what the basic and novel characteristics of the claimed invention actually are. Applicant has the burden of showing that the introduction of additional components would materially change the characteristics of applicant's invention. Furthermore, it is noted that Meijer *et al.* teach that in a preferred embodiment, all twelve listed HPV types are present, but also teaches that the probe cocktail can be present as two or more different probe mixtures, thus teaching smaller groupings of HPV probes (p. 18, lines 20-24).

11. Claims 1, 4, and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Troncone *et al.* (J. Clin. Pathol. 1992, Vol. 45:308-313).

Troncone *et al.* teach a reagent for detecting human papillomavirus DNA comprising a plurality of DNA probes capable of specifically hybridizing to high-risk HPV DNA but not low-risk HPV DNA. In particular, Troncone *et al.* teach a cocktail of full length genomic probes that are specific to HPV types 16, 18, and 33 (p. 309, "NISH ON CERVICAL SMEARS").

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Meijer *et al.* in view of Orth *et al.* (US 5981173).

Meijer *et al.* teach a reagent for detecting human papillomavirus DNA comprising a plurality of DNA probes capable of specifically hybridizing to high-risk HPV DNA but not low-

risk HPV DNA. In particular, Meijer *et al.* teach a mixture of probes specific for HPV types 16, 18, 31, 33, 35, 39, 45, 51, 52, 54, 56, and 58, and that this mixture does not contain proves specific for a variety of "low risk" HPV types (p. 16, lines 15-23). Meijer *et al.* further teach that it is advisable to add HPV 59 to the high risk reagent and suggest that the probe cocktail needs to be supplemented when new identified high risk HPVs are found (p. 16, line 26-p. 17, line 5).

Meijer *et al.* do not teach a reagent that hybridizes to HPV types 68 and 70.

Orth *et al.* teach the genomes of HPV68 and HPV70 and teach that they were cloned from cervical interepithelial neoplasia (ABSTRACT, and throughout). Orth *et al.* teach oligonucleotide probes for the detection of HPV types 68 and 70 (Col. 3, lines 34-44) and teach that these probes can be used in combination with probes derived from other HPV (Col. 3, lines 54-56).

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have included probes specific for HPV 68 and HPV 70 in the reagents taught by Meijer *et al.* The ordinary practitioner would have been motivated to include the probes to the additionally HPV types in order to follow the explicit guidance provided by Meijer *et al.* to include additional HPV probes for a more complete set of probes for detection of HPV that lead to high risk for the development of cancer.

15. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Meijer *et al.* in view of Bauer *et al.* (US 5639871).

Meijer *et al.* teach a reagent for detecting human papillomavirus DNA comprising a plurality of DNA probes capable of specifically hybridizing to high-risk HPV DNA but not low-risk HPV DNA. In particular, Meijer *et al.* teach a mixture of probes specific for HPV types 16,

18, 31, 33, 35, 39, 45, 51, 52, 54, 56, and 58, and that this mixture does not contain proves specific for a variety of "low risk" HPV types (p. 16, lines 15-23). Meijer *et al.* further teach that it is advisable to add HPV 59 to the high risk reagent and suggest that the probe cocktail needs to be supplemented when new identified high risk HPVs are found (p. 16, line 26-p. 17, line 5).

Meijer *et al.* do not teach a reagent having probes in the concentrations given in claim 7. However, the optimization of hybridization assays by determining ideal probe concentrations was routine in the prior art at the time the invention was made, as is exemplified by Bauer *et al.* who teach "The optimal ratio and concentration of probe fragments to be used in the hybridization are determined empirically (Col. 51, lines 60-63)."

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have experimented with different probe concentrations so as to arrive at an optimal concentration for the detection of HPV in a sample. It is well settled that routine optimization is not patentable, even if it results in significant improvements over the prior art. In support of this position, attention is directed to the decision in *In re Aller, Lacey, and Hall*, 105 USPQ 233 (CCPA 1955):

> Normally, it is to be expected that a change in temperature, or in concentration, or in both, would be an unpatentable modification. Under some circumstances, however, changes such as these may impart patentability to a process if the particular ranges claimed produce a new and unexpected result which is different in kind and not merely in degree from the results of the prior art. In re Dreyfus, 22 C.C.P.A. (Patents) 830, 73 F.2d 931, 24 USPQ 52 ; In re Waite et al., 35 C.C.P.A. (Patents) 1117, 168 F.2d 104, 77 USPQ 586 . Such ranges are termed "critical" ranges, and the applicant has the burden of proving such criticality. In re Swenson et al., 30 C.C.P.A. (Patents) 809, 132 F.2d 1020, 56 USPQ 372 ; In re Scherl, 33 C.C.P.A. (Patents) 1193, 156 F.2d 72, 70 USPQ 204 . However, even though applicant's modification results in great improvement and utility over the prior art, it may still not be patentable if the modification was within the capabilities of one skilled in the art. In re Sola, 22 C.C.P.A. (Patents) 1313, 77 F.2d 627, 25 USPQ 433 ; In re Normann et al., 32 C.C.P.A. (Patents) 1248, 150 F.2d 708, 66 USPQ 308 ; In re Irmscher, 32 C.C.P.A. (Patents) 1259, 150 F.2d 705, 66 USPQ 314 . More

> particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. In re Swain et al., 33 C.C.P.A. (Patents) 1250, 156 F.2d 239, 70 USPQ 412 ; Minnesota Mining and Mfg. Co. v. Coe, 69 App. D.C. 217, 99 F.2d 986, 38 USPQ 213 ; Allen et al. v. Coe, 77 App. D. C. 324, 135 F.2d 11, 57 USPQ 136. (Emphasis added)

For these reasons, the claimed invention is *prima facie* obvious.

16. Claims 17, 18, 20, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meijer *et al.* in view of the 1988 Stratagene Catalog.

Meijer *et al.* teach a reagent for detecting human papillomavirus DNA comprising a plurality of DNA probes capable of specifically hybridizing to high-risk HPV DNA but not low-risk HPV DNA. In particular, Meijer *et al.* teach a mixture of probes specific for HPV types 16, 18, 31, 33, 35, 39, 45, 51, 52, 54, 56, and 58, and that this mixture does not contain proves specific for a variety of "low risk" HPV types (p. 16, lines 15-23).

With regard to claim 5, these probes are considered "full length" because an entire probe is given, and Meijer *et al.* teach using the full length of the probe in the reagent. The claim does not further define "full length" and thus the broadest reasonable interpretation of the claim is given.

With regard to claim 6, which recites that the reagent is "consisting essentially of" DNA probes to HPV types 16, 18, 31, 33, 35 and 51, in accordance with MPEP 2111.03, this transitional language is being interpreted to be the equivalent of "comprising" as there has been no clear indication in the specification of what the basic and novel characteristics of the claimed invention actually are. Applicant has the burden of showing that the introduction of additional components would materially change the characteristics of applicant's invention. Furthermore, it is noted that Meijer *et al.* teach that in a preferred embodiment, all twelve listed HPV types are

present, but also teaches that the probe cocktail can be present as two or more different probe mixtures, thus teaching smaller groupings of HPV probes (p. 18, lines 20-24).

Meijer *et al.* do not teach kits wherein the reagents are in containers.

Stratagene teaches gene characterization kits. The ordinary practitioner would have been motivated to have produced such a kit because since the Stratagene catalog expressly teaches the benefits to the practitioner of kits:

> "Each kit provides two services: 1) a variety of different reagents have been assembled and pre-mixed specifically for a defined set of experiments. When one considers all of the unused chemicals that typically accumulate in weighing rooms, desiccators, and freezers, one quickly realizes that it is actually more expensive for a small number of users to prepare most buffer solutions from the basic reagents. Stratagene provides only the quantities you will actually need, pre-mixed and tested. In actuality, the kit format saves money and resources for everyone by dramatically reducing waste. 2) The other service provided in a kit is quality control."

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at tee time the invention was made to have packaged the reagents taught by Meijer *et al.* into containers for distribution in a kit. The ordinary practitioner would have been motivated to provide such kits in order to provide consumers with the convenience of kits for the detection of HPV in samples, since Stratagene expressly describes the benefits of such kits. Therefore, the kits of the instant claims are *prima facie* obvious over the disclosure of Meijer *et al.* in view of the Stratagene catalog.

17. Claims 17 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Troncone *et al.* in view of Stratagene 1988 Catalog.

Troncone *et al.* teach a reagent for detecting human papillomavirus DNA comprising a plurality of DNA probes capable of specifically hybridizing to high-risk HPV DNA but not low-

risk HPV DNA. In particular, Troncone *et al.* teach a cocktail of full length genomic probes that are specific to HPV types 16, 18, and 33 (p. 309, "NISH ON CERVICAL SMEARS").

Troncone *et al.* do not teach kits wherein the reagents are in containers.

Stratagene teaches gene characterization kits. The ordinary practitioner would have been motivated to have produced such a kit because since the Stratagene catalog expressly teaches the benefits to the practitioner of kits:

> "Each kit provides two services: 1) a variety of different reagents have been assembled and pre-mixed specifically for a defined set of experiments. When one considers all of the unused chemicals that typically accumulate in weighing rooms, desiccators, and freezers, one quickly realizes that it is actually more expensive for a small number of users to prepare most buffer solutions from the basic reagents. Stratagene provides only the quantities you will actually need, pre-mixed and tested. In actuality, the kit format saves money and resources for everyone by dramatically reducing waste. 2) The other service provided in a kit is quality control."

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at tee time the invention was made to have packaged the reagents taught by Troncone *et al.* into containers for distribution in a kit. The ordinary practitioner would have been motivated to provide such kits in order to provide consumers with the convenience of kits for the detection of HPV in samples, since Stratagene expressly describes the benefits of such kits. Therefore, the kits of the instant claims are *prima facie* obvious over the disclosure of Troncone *et al.* in view of the Stratagene catalog.

18. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Meijer *et al.* in view of Orth *et al.* as applied to claim 3 above, and further in view of Stratagene 1988 catalog.

The particular teachings of Meijer *et al.* in view of Orth *et al.* with respect to claim 3 are set forth in the previous rejection. Meijer *et al.* in view of Orth *et al.* further do not teach kits wherein the reagents are in containers..

Stratagene teaches gene characterization kits. The ordinary practitioner would have been motivated to have produced such a kit because since the Stratagene catalog expressly teaches the benefits to the practitioner of kits:

> "Each kit provides two services: 1) a variety of different reagents have been assembled and pre-mixed specifically for a defined set of experiments. When one considers all of the unused chemicals that typically accumulate in weighing rooms, desiccators, and freezers, one quickly realizes that it is actually more expensive for a small number of users to prepare most buffer solutions from the basic reagents. Stratagene provides only the quantities you will actually need, pre-mixed and tested. In actuality, the kit format saves money and resources for everyone by dramatically reducing waste. 2) The other service provided in a kit is quality control."

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have packaged the reagents taught by Meijer *et al.* in view of Orth *et al.* into containers for distribution in a kit. The ordinary practitioner would have been motivated to provide such kits in order to provide consumers with the convenience of kits for the detection of HPV in samples, since Stratagene expressly describes the benefits of such kits. Therefore, the kits of the instant claims are *prima facie* obvious over the disclosure of Meijer *et al.* in view of Orth *et al.* and further in view of the Stratagene catalog.

19. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Meijer *et al.* in view of Bauer *et al.* as applied to claim 7 above, and further in view of Stratagene 1988 catalog.

The particular teachings of Meijer *et al.* in view of Bauer *et al.* with respect to claim 7 are set forth in the previous rejection. Meijer *et al.* in view of Bauer *et al.* further do not teach kits wherein the reagents are in containers.

Stratagene teaches gene characterization kits. The ordinary practitioner would have been motivated to have produced such a kit because since the Stratagene catalog expressly teaches the benefits to the practitioner of kits:

> "Each kit provides two services: 1) a variety of different reagents have been assembled and pre-mixed specifically for a defined set of experiments. When one considers all of the unused chemicals that typically accumulate in weighing rooms, desiccators, and freezers, one quickly realizes that it is actually more expensive for a small number of users to prepare most buffer solutions from the basic reagents. Stratagene provides only the quantities you will actually need, pre-mixed and tested. In actuality, the kit format saves money and resources for everyone by dramatically reducing waste. 2) The other service provided in a kit is quality control."

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have packaged the reagents taught by Meijer *et al.* in view of Bauer *et al.* into containers for distribution in a kit. The ordinary practitioner would have been motivated to provide such kits in order to provide consumers with the convenience of kits for the detection of HPV in samples, since Stratagene expressly describes the benefits of such kits. Therefore, the kits of the instant claims are *prima facie* obvious over the disclosure of Meijer *et al.* in view of Bauer *et al.* and further in view of the Stratagene catalog.

Conclusion

20. No claims are allowed.

21. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Faulkner-Jones *et al.* (Journal of Virological Methods, 41 (1993) 277-296) teach that for DNA detection the use of full length genomic probes is preferred over oligonucleotide probes because full length genomic probes are more sensitive. They teach that for RNA detection oligonucleotide probes are more sensitive.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C. Switzer whose telephone number is (703) 306-5824. The examiner can normally be reached on Monday through Friday, from 9:00 AM until 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

JEFFREY FREDMAN
PRIMARY EXAMINER

Juliet C. Switzer
Examiner
Art Unit 1634

June 24, 2003